K030133

APR 2 9 2003

Star Dental Products
1816 Colonial Village Lane
Lancaster, PA 17601-5864
717/291-1161
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510(k) Summary
Solara Series High Speed Dental Handpieces
January 10, 2003

Company:

StarDental, Div. DentalEz Inc.
Owner/operator number 2520265

Contact Person:

William Guscott
Engineering Manager
StarDental, Div. DentalEz Inc.
1816 Colonial Village Lane
Lancaster, PA 17601
Phone: (717) 291-1161, ext. 4319
Fax: (717) 391-2757

Proprietary/Trade Name:

Solara Series High Speed Dental Handpieces, which includes Solara High Speed Dental Handpiece and Solara Plus High Speed Dental Handpiece

Common/Usual Name:

Dental Handpiece

Classification:

Dental handpiece and accessories (per 21 CFR 872.4200)

Predicate Device:

StarDental 430 Series High Speed Handpiece (K960719 and K 982593)
NSK TI-Max Titanium Handpiece

Device Description/Intended Use:

The Solara Series High Speed Dental Handpieces are pneumatically driven, hand-held devices intended for use by trained dental professionals for drilling in the oral cavity. Procedures include but not limited caries removal, restorative work and crown preparations.

Substantial Equivalence:

The determination of substantial equivalence is based on the premise that the proposed device and the predicate devices have the same intended use, similar technology and design. Both devices have the same means of operation and are used for the same procedures. Improvements made to the proposed device were initiated to improve the handpiece performance while maintaining the safety of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. William Guscott
Engineering Manager
DentalEZ, Incorporated
Star Dental Products Division
1816 Colonial Village Lane
Lancaster, Pennsylvania 17601-5864

Re: K030133
Trade/Device Name: Solara Series Comprised of the Solara High Speed Dental Handpiece and the Solara Plus High Speed Dental Handpiece
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EBF
Dated: April 7, 2003
Received: April 9, 2003

Dear Mr. Guscott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030133

Device Name: Solara Series Comprised of the Solara High Speed Dental Handpiece and the Solara

Indications For Use:

High speed handpieces are used intraorally by trained dental professionals for drilling and preparation of dental cavities for restoration, such as fillings. The intended use of this device is identical to the predicate 430 series handpiece currently marketed under 510(k) numbers K960719 and K982593.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Robert S Beltz DDS for Dr KP Mulley

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030133